The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities

SUPPORTING STATEMENT

A. Justification

1. Circumstances Which Make This Information Collection Necessary

The Office of Counter-Terrorism and Pediatric Drug Development (OCTAP) in the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is requesting emergency OMB Clearance to conduct a survey entitled "The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities". As a result of the terrorist events during the Fall of 2001, a number of Federal Government facilities were contaminated with residual anthrax spores. As a result of this exposure, the Federal Government contracted to have the facilities decontaminated. This clean up work has been on going since late September 2001. The workers employed in the decontamination effort were placed on long-term prophylactic antibiotics. FDA wishes to systematically evaluate these decontamination workers for adverse events they may have experienced as a result of their exposure to long-term prophylactic antibiotics. Because the stress of being a victim of a terrorist act can in itself cause many symptoms that are similar to adverse events that might be caused by various drug therapies, it is extremely important that FDA obtain information on individuals who took these antibiotics but were not subjected to the anxiety and stress associated with a terrorist event. This type of population is likely never again to be available for assessment unless a future terrorist event occurs. It is necessary for FDA to obtain drug experience information from this group to assist in any future public health response to a terrorist attack.

The statutory authority that allows the FDA to collect this information is Section 301 of the PHS Act (42 USC Sec. 241). This statute authorizes the Secretary to render assistance and promote the coordination of research investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man.

2. How, By Whom, and the Purpose of Collecting This Information

Through the services of a contractor, the FDA plans to administer a survey to approximately 1,200 decontamination workers who were placed on long-term antibiotic therapy to protect them from environmental anthrax spores. These 1,200 decontamination workers are divided into 2 groups. One group consists of approximately 800 decontamination workers that

left a site without being offered a post-antibiotic follow-up visit. The remaining 400 decontamination workers will be offered a post-antibiotic follow-up visit after leaving a site. These 400 will be advised to take an additional 60 days of antibiotics. If a worker declines to take their antibiotics for 60 additional days, then 10 days after having taken their last antibiotic dose, they are directed to participate in a post-antibiotic follow-up visit, which is conducted by the medical service subcontractor. If the decontamination worker agrees to take antibiotics for an additional 60 days after leaving the site, then the post antibiotic visit is delayed until 10 days after the final antibiotics are taken. With the cooperation of the medical service subcontractor, the contractor shall participate in these post-antibiotic follow-up visits, via the telephone and administer the survey instrument.

The collection of information will be conducted via the telephone by administering a questionnaire that was developed for this purpose.

The purpose of collecting this information is to enhance FDA's ability to apply lessons learned from the current situation in order to provide better guidance needed to protect the public health during future terrorist events should they occur.

3. Use of Technology to Reduce the Burden on the Public

As appropriate, automated information technology will be used to collect and process information for this survey to reduce the burden on the public. Oral responses to a brief questionnaire will, however, be the primary method employed in administering the questionnaire.

4. Identification and Use of Duplicate Information

This survey will not duplicate any other studies. Although CDC conducted a similar survey approved by OMB (0920-0543) this study will be looking at a different cohort of people. The CDC survey was to study adverse events in individuals placed on long-term prophylactic antibiotics who were exposed to anthrax spores during a terrorist event. The FDA survey will be to study adverse events in individuals placed on long-term prophylactic antibiotics who worked in anthrax contaminated facilities after the terrorist attack..

5. FDA's Efforts to Reduce Burden on Small Business

No small business will be involved in this collection.

6. Impact of Not Collecting this Information or Collecting Information Less Frequently

Failure of FDA to adequately follow up on these workers will lessen the Agency's ability to apply lessons learned from the current situation to provide guidance during future public health emergencies should they occur. This could result, not only in the loss of time and dollars, but also in the loss of human life if patients stop taking their medicines because they think the drug therapy is responsible for a health problem when in fact it is not.

FDA will administer the questionnaire only once to each affected decontamination worker. There are no technical or legal obstacles to reducing burden.

7. Information Collection Circumstances

There are no special circumstances pertaining to the collection of this information.

8. Identification of Outside FDA Sources

The FDA used agency experts as well as outside experts to develop the survey instrument in final format. The FDA is also seeking public comment with a Federal Register notice announcing the survey.

9. Payment or Gifts Offered to Respondents

No payment or gifts will be provided to survey respondents.

10. Method of Ensuring Respondent Confidentiality

Confidentiality of respondent information will be ensured to the maximum extent allowed by law. Participation will be voluntary. The information collection will comply with the Privacy Act. Respondents will be assured that neither their participation, non-participation, nor their responses to items will affect FDA's attitude toward them.

11. Use of Sensitive Questions

Respondents will not be required to disclose any sensitive information as a result of participating in the survey.

12. Burden of Information Collection

The total estimated burden is 300 hours. This estimate is based on a similar survey instrument (0920-0543) that was administered by CDC to individuals who were exposed to anthrax spores dispersed during a terrorist event. FDA

hopes to be able to reach the entire population of approximately 1,200 decontamination workers.

Estimated Annual Reporting Burden[1]

Type of Survey	Number of Respondents	Annual Frequency of Response	Total Annual Response	Hours per Response	Total Hours
Telephone	1,200	1	1,200	.25	300
Total					300

[1]There is no capital costs or operating and maintenance costs associated with this collection of information.

13. Annual Cost Estimate to Respondents

The only cost to respondents will be the value of their time spent in responding.

14. Annual Cost Estimate to FDA

The FDA estimates the cost to collect this information will be approximately $181,000. This estimate was based on the following:

Labor (2,800 hours for Project Director, Senior Survey Specialist, Interviewers and Admin Support):	$68,000
Fringe Benefits at 38%:	25,840
Other Direct Costs (Travel, telephone, copying, misc.):	18,000
General and Administrative costs at 50%:	55,920
Fee (or profit) at 8%:	13,421
Total:	$181,181

15. Changes from Previous Approval

This is a new collection.

16. Publishing the Results of this Information Collection

The FDA will perform descriptive analyses on this population (cohort) to include frequency distributions for demographic, drug compliance, and drug adverse events.

The Centers for Disease Control and Prevention (CDC) recently employed a contractor to survey approximately 10,000 individuals who received antibiotics to prevent the occurrence of anthrax in individuals (OMB No. 0920-0543). The FDA plans to compare the adverse event rates measured in that cohort to those observed in individuals involved with anthrax decontamination work who received long term antibiotics. This

comparison will serve to distinguish terror-related health effects from long-term antibiotic use health effects.

Data collection will begin around the end of September 2002. We anticipate that all data collection will be completed by the end of March 2003. Once data collection is complete, the contractor shall submit a report, including electronic datasets using a SAS Program, to the FDA. Following submission of this report, a new contract mechanism will be sought for the formal analysis of these data. Once this new contract mechanism is in place, a timeframe for publication will become clearer.

17. Reason for Not Displaying the OMB Approval Date

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exception to "Certification for Paperwork Reduction Act Submissions"

With the exception of point 19(i) on OMB Form 83-I these activities will comply with Paperwork Reduction Act requirements. However we can not certify the "use of effective and efficient statistical survey methodology" until we determine how we will statistically compare the decontamination cohort to the CDC cohort. As explained in item A.16 above, the FDA plans on awarding a new contract mechanism for the formal analysis of the data at which time we will be able to determine the most effective and efficient statistical survey methodology to employee.

B. Collections of Information Using Statistical Methods

1. Potential Respondent Universe and Sample Selection Method

The entire population of decontamination workers is approximately 1,200 individuals. The FDA plans on administering the survey instrument to all 1,200 workers. In particular there are better than 400 decontamination workers at the Brentwood Post Office facility who have not stopped taking their antibiotics. These workers are scheduled for a final medical examination 10 days after the final antibiotic is taken at which time these workers will be offered an opportunity to continue to take the antibiotic for an additional 60 days. For those workers that elect to continue to take antibiotics for 60 additional days, FDA will still administer the survey instrument 10 days after their final antibiotic (60 days later) is taken when they present for their final post-antibiotic medical examination.

Based on experience with similar surveys FDA anticipates that of these 400 plus workers 90%, or better, will participate in the survey. For the remaining 800 decontamination workers FDA anticipates that approximately 50% will

participate in the survey. Although 50% is a low percentage of the workers to participate, this type of population is likely to never again to be available for assessment unless a future terrorist event occurs. Therefore it is important that the FDA obtain drug experience information regarding adverse events among workers who received long-term antibiotics to assist in any future public health response to a terrorist attack.

2. Procedures for Collecting the Information

FDA will collect all information via the telephone. For workers who present for their final medical examination, as part of that examination, they will be provided with an 800-telephone number to call at which time the survey will be administered. For workers who do not present for their final medical examination or where a final medical examination was not offered, the contractor will telephone these individuals directly. If the contractor is not able to make contact with the worker during the initial telephone call, the contractor shall follow up on that individual for up to three additional times. Since approximately 20% of the decontamination workers are Spanish speaking, the survey instrument will be translated into Spanish.

FDA will collect the minimum information necessary in order to evaluate the adverse events that the administration of long-term antibiotics may have had on these workers. All responses will remain strictly confidential, and the FDA will guarantee to all survey participants that their responses will remain private.

3. Methods to Increase or Maximize the Response Rate

Consistent with sound survey methodology, FDA will use all available tools to maximize the response rates. The design of the survey instrument included approaches to maximize response, while retaining the voluntary nature of the effort. For example the survey instrument will be translated into Spanish and administered by Spanish speaking interviewers where appropriate. For those individuals that the contractor calls directly, the contractor shall make up to 3 additional attempts to contact a worker before that individual is dropped from the survey.

4. Identify Test, Procedures or Methods Used

The survey instrument to be employed in the collection of data under this study is very similar to the survey instrument that CDC used to collect data on individuals provided long-term antimicrobial therapy as a result of exposure to anthrax spores from a terrorist attack. The survey instrument used by CDC was approved by OMB under reference No. 0920-0543. Whereas FDA will be using many of the same elements of the survey instrument employed by CDC, no pretest of the survey instrument will be administered.

5. Identification of Consultations

The survey instrument was based on the instrument used by CDC (OMB No. 0920-0543) to evaluate individuals who were administered long-term antibiotics as a result of potential exposure to anthrax spores. The Office of Counter-Terrorism and Pediatric Drug Development of the Center for Drug Evaluation and Research (CDER), FDA with input from Dr. Gerald Berke, MD, of Health Resources, 600 West Cummings Park, Suite 3400, Woburn, Massachusetts 01801-6350 developed the draft Questionnaire that is attached. The FDA plans on awarding a contract to Market Facts, Incorporated, 1650 Tysons Boulevard, Suite 110, McLean, VA 22102 to administer the questionnaire. Prior to its implementation and in order to maximize the effective administration of the questionnaire, the contractor shall review it and provide comments to the FDA Project Officer on the best methodology to employee in presenting the questions to the decontamination workers. Due to the urgency of collecting the data from the 400 plus workers scheduled for final medical examinations to start in earnest in mid September, FDA's immediate need is information collection. Therefore, at this time, the FDA is not requesting that the information be analyzed. FDA will analyze the data at a later date under another contract vehicle, either back to Market Facts, Inc. or by another appropriate contract vehicle.